Docket No. 366325-509
US App. No. 10/036,487

REMARKS

Claims 1-8 and 10-22 are currently pending in this application. Claim 23 has been canceled. Claims 20, 21, and 22 have been amended. No new matter has been added. The amendments merely present the claim language in a clearer fashion and introduce the limitations of a dependent claim into an independent claim.

The following remarks put the pending claims in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims.

35 U.S.C. § 102 Rejections

35 USC § 102(b) Rejection by Lorenz et al.

Claims 1-4, 6-8 20 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lorenz et al., U.S. Patent No. 5,420,197, (hereinafter "Lorenz").

The Office alleges that Lorenz discloses a composition that comprises a polyvinylpyrrolidone, wetting, dispersing agents or surfactants, glycerin and polyethylene glycol, biologically active agents or cosmetic agents and fragrances, dyes, pigments and fillers. The Office further alleges that Lorenz teaches application of the composition to wet skin and would inherently clean the skin. Further, the Office Action states that the recitation of the delivery disc's dissolution properties "refers to what happens to the delivery device."

Applicants traverse this rejection and respectfully assert that the pending claims are not anticipated by Lorenz. Claim 1 recites a delivery disc comprising a filmogenic polymer and an effective dose of an active substance, wherein the delivery disc is a single uniform layer device which is non-tacky and which dissolves onto a wetted skin tissue or mucosal epithelial tissue of a subject when applied thereto. Claim 20 recites a method of administering an active substance to subject comprising:

> wetting a skin tissue of the subject at a site of application; and
> applying to the site of application a delivery disc...;

> wherein upon application to the wetted skin tissue, the delivery disc dissolves.

The dissolution of the delivery disc on the wetted skin tissue or mucosal epithelial tissue is an integral property of the invention and must be addressed by any prior art rejection. In contrast to the present invention, Lorenz teaches chitosan gels that are highly water absorbent. For example, Lorenz teaches that the "gels are stable and therefore maintain there physical integrity after absorbing large quantities of liquid" (see col. 4, lines 59-62). Lorenz further teaches gels used as an adsorbent wound packing agents that becomes "saturated with would exudate" (see col. 6, lines 65-68). Lorenz further teaches gels used as face masks that "can easily be peeled off after use" (see column 7, lines 10-12). Lorenz also provides specific examples wherein gels are formed that do not dissolve or disintegrate. In Example 5, Lorenz teaches applying a gel to wet human skin. The gel "could be rolled or peeled from the skin." Lorenz then expressly teaches that the gel does not dissolve even in large amounts of liquid (see col. 7, lines 59-64):

> The gel, when put in excess water or saline solution at room temperature, absorbed additional liquid but did not dissolve or disintegrate.

Lorenz reiterates this property in example 6 (see col. 8, lines 5-10). Based on the full disclosure of Lorenz, it is clear that the chitosan gels of Lorenz do not meet the limitation of the claims reciting the dissolution properties of the delivery disc of the instant invention.

Claim 22 as amended recites a method for cleansing skin tissue of a subject comprising:

> wetting the skin tissue of the subject to be cleansed;
> applying a delivery disc to the wet skin tissue; and...
> creating a foam or lather with the delivery disc on the wet skin tissue and rinsing the delivery discs from the skin.

As detailed above, Lorenz teaches gels that are highly water absorbent. Lorenz provides no teaching of creating a foam or lather with the gels. Lorenz further provides specific examples of gels that do not dissolve or disintegrate and maintain their structural

integrity when placed in large amounts of liquid. These teachings certainly fail to meet the limitation of creating a foam or lather with the delivery disc since a gel cannot maintain its structural integrity and simultaneously change its form into a foam or lather.

For anticipation, a reference must teach each and every limitation of the claims. "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention" *Hybritiech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed Cir. 1986). "Anticipation under 35 U.S.C. §102 requires the disclosure in a single piece of prior art each and every limitation of a claimed invention" *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000) quoting *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994).

Since Lorenz fails to teach a delivery disc that dissolves onto a wetted skin tissue or mucosal epithelial tissue when applied thereto and actually expressly teaches gels that do not dissolve even in large amounts of liquid; Lorenz cannot anticipate claims 1-4, 6-8, and 20 of the present invention. Furthermore, since Lorenz fails to teach a method wherein the delivery disc forms a foam or lather and actually expressly teaches gels that maintain their structural integrity even in large amounts of liquid, Lorenz cannot anticipate claim 22 of the present invention. Accordingly, Applicants respectfully request that the rejection of claims 1-4, 6-8, 20, and 22 under 35 U.S.C. §102(b) be withdrawn.

35 USC § 102(b) Rejection by Leonard et al.

Claims 1, 3, and 21 stand rejected under 35 U.S.C. §102(b) as being anticipated by Leonard et al., U.S. Patent No. 4,820,525, (hereinafter "Leonard").

The Office Action alleges that Leonard discloses a transdermal delivery system that comprises a polyethylene polymer and estradiol in the form of disk. The Office further alleges that transmucosal delivery system in a disk form implies application of a composition comprising estradiol and polyethylene polymer to the mucosa. The Office further states that the recitation of the dissolution of the delivery disc is either irrelevant or inherent in the teachings of Leonard.

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Applicants traverse this rejection and respectfully assert that the pending claims are not anticipated by Leonard. Claim 1 recites a delivery disc comprising a filmogenic polymer and an effective dose of an active substance, wherein the delivery disc is a single uniform layer device which is non-tacky and which dissolves onto a wetted skin tissue or mucosal epithelial tissue of a subject when applied thereto. Claim 21 recites a method of administering an active substance to subject comprising: applying a delivery disc to a mucosal epithelial layer of the subject, wherein upon application to the mucosal epithelial layer, the delivery disc dissolves.

The dissolution of the delivery disc on the wetted skin tissue or mucosal epithelial tissue is an integral property of the invention and must be addressed by any prior art rejection. In contrast to the present invention, Leonard teaches drug reservoir foam that delivers a drug via a transdermal or transmucosal pathway over an extended period of time. Leonard fails to teach wherein the foam dissolves upon application to wetted skin tissue or mucosal epithelial tissue. In fact, Leonard provides examples wherein the foam is removed after 24 hours of application to a subject (see col. 3, lines 8-10 and 30-31). Clearly, the foam patches of Leonard are simply holding mechanisms or reservoirs for drugs and do not have the dissolution properties of the delivery discs of the instant invention.

For anticipation, a reference must teach each and every limitation of the claims. "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention" *Hybritiech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed Cir. 1986). "Anticipation under 35 U.S.C. §102 requires the disclosure in a single piece of prior art each and every limitation of a claimed invention" *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000) quoting *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994).

Since Leonard fails to teach a delivery disc that dissolves onto a wetted skin tissue or mucosal epithelial tissue when applied thereto and actually expressly teaches foams that do not dissolve over a 24 hour period of application to a subject; Leonard cannot anticipate claims 1, 3, and 21 of the present invention. Accordingly, Applicants

respectfully request that the rejection of claims 1, 3, and 21 under 35 U.S.C. §102(b) be withdrawn.

35 U.S.C. § 103(a) Rejections

35 USC § 103(a) Rejection over Lorenz et al.

Claims 10-19 and 23 stand rejected under 35 U.S.C. 103(a) for allegedly being obvious over Lorenz et al., U.S. Patent No. 5,420,197, (hereinafter "Lorenz").

Applicants respectfully traverse this rejection. As detailed above, Lorenz fails to teach or suggest a delivery disc that dissolves when applied to wetted skin tissue or mucosal epithelial tissue. Indeed, Lorenz actually teaches away from such a property by teaching gels that do not dissolve or disintegrate even when placed in large amounts of liquid. Lorenz further fails to teach or suggest a method of cleansing a skin tissue comprising applying a delivery disc to wetted skin tissue; and creating a foam or lather with the delivery disc on the wetted skin tissue. In fact, Lorenz actually teaches away from such a method by teaching gels that maintain their structural integrity upon application to a subject. Since Lorenz fails to teach or suggest all the limitations of the claims, Lorenz cannot render the claims obvious. Therefore, at least for the preceding reasons, Applicants respectfully request that the rejection of claims 10-19 and 23 under 35 U.S.C. § 103(a) be withdrawn.

Double Patenting

Obviousness-type Double Patenting Rejection over U.S. App. 09/340,338

Claims 1, 3, 6, 8, and 15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42, 43, and 45-47 of U.S. App. No. 09/340,338.

Applicants respectfully request that this provisional rejection be held in abeyance until indication of allowable subject matter. At that time, Applicants will fully respond to

the merits of the rejection if necessary. The Office's attention is brought to MPEP 804 which states:

> The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

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CONCLUSION

Applicants believe this response to be a full and complete response to the Office Action. In view of the foregoing, Applicants respectfully request reconsideration and allowance of claims 1-8 and 10-22. As the application is believed to be in condition for allowance, Applicants respectfully request a Notice of Allowability. The Examiner is invited to contact the undersigned representative should any further issues arise

Respectfully submitted,

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